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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,077	05/15/2006	Shintaro Kobayashi	P28961	1087

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GREENBLUM & BERNSTEIN, P.L.C.
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RESTON, VA 20191

EXAMINER

IQBAL, SYED TAHA

ART UNIT	PAPER NUMBER
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1793

NOTIFICATION DATE	DELIVERY MODE
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08/12/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/560,077	Applicant(s) KOBAYASHI ET AL.	
	Examiner SYED IQBAL	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/19/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Upon further consideration, the restriction requirement, of 11/25/2008, is withdrawn. Claims 1-17 are pending. Among these 2, 4 and 5 are cancelled. Claims 1, 3 and 6-17 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description support for the recitation "...no change occurs in the composition of the apatite due to the bonding of Fe³⁺..."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim suggests that there is no change in the composition of the apatite when iron bonds to the composition. However, if a new element is bonded

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to a composition that composition has been changed anyways. Further clarification is required.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 3, 6 and 7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Atsumi JP10118167.

In regards to claim 1, Atsumi teaches (Pg 21 Para [0030]) the compounds $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ and $\text{Ca}_{10}(\text{PO}_4)_6(\text{X})_2$, where X is a halogen, which are species of the formula $\text{Ca}_{10}(\text{PO}_4)_6((\text{OH})_{1-x}\text{A}_x)_2$ recited in instant claim 1, wherein the x may be 0 and 1. Atsumi also teaches trivalent iron from an iron nitrate source may be bonded to the phosphate group of the compounds discussed above (Pg 51 Para [0097]). The functional language in the preamble does not incur any limitations which have patentable weight. The limitations regarding the physical properties or abilities of the compound would be inherent to the composition which is anticipated by the reference.

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In regards to claim 3, the reference gives examples of the amounts of Fe^{+3} that are on the apatite. The weight percents of the metals are disclosed (Pg 41 table A). For instance, in example 1, 1 wt% and in example 11, 10 wt% of Fe was used per 135g of apatite (Pg 32 Para [0055]), which would fall within the range of 0.1 to 100 mg per gram of the apatite.

In regards to claim 6 and 7, the reference discloses species $\text{Ca}_{10}(\text{PO}_4)_6\text{F}_2$ (Pg20 Para [0027]) of the genus of instant claim 1. This relates to the instant formula (from instant claim 1) when x is considered 1 and A is F. Since the species is disclosed the genus is anticipated.

Accordingly the claims are anticipated by the reference. In any event, the claims would also be obvious over the reference. The reference does not expressly state all the properties and capabilities of the product, such as being able to adsorb a phosphorylated protein. Nevertheless it would be obvious to use the sorbent in any type of adsorption as it would not lead to any unexpected results.

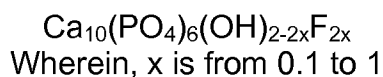
Claims 8-16 are rejected under 35 U.S.C. 103(a) as obvious over Atsumi JP10118167, in view of Ichitsuka et al. US5651884.

Regarding claims 8-12, Atsumi teaches the hydroxy apatite adsorbent and a trivalent ion of Fe^{3+} . However, Atsumi does not expressly state an apparatus comprising a column.

Ichitsuka et al teaches a packing material for liquid chromatography (Abstract) useful in applications such as blood treatment with columns and liquid chromatography used in separating and purifying proteins, enzymes, nucleic acid phosphoric acid etc.

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The material comprises at least one material selected from the group consisting of $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$, $\text{Ca}_3(\text{PO}_4)_2$, $\text{Ca}_2\text{P}_2\text{O}_7$, $\text{Ca}(\text{PO}_3)_2$, $\text{Ca}_{10}(\text{PO}_4)_6\text{F}_2$ and $\text{Ca}_{10}(\text{PO}_4)_6\text{Cl}_2$. A particle size of 2 to 100 μm is also taught (Col. 9 line 27). Also taught is packing for liquid chromatography comprising fluoroapatite represented by the formula:



Ichitsuka discloses packing the packing material in a column and passing a mobile phase over it (Col. 10 line 10 and line 48). There is no suggestion of a non-uniform composition through out the column.

At the time of invention it would have been obvious to one having an ordinary level of skill in the art to use the composition of Atsumi as the packing material in the column of Ichitsuka. One would be motivated to do because the adsorbent composition of Atsumi is substantially similar to that of Ichitsuka and there would not be any unpredictable results from the substitution in the column. Furthermore, one having an ordinary level of skill in the art would also envisage to fully and uniformly pack a chromatography column.

Regarding claim 13, Atsumi teaches using a slurry to contact the apatite and the iron (Para [0055] and [0056]).

Ichitsuka teaches the use of a similar apatite composition in a chromatography column type apparatus.

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At the time of invention it would have been obvious to use the chromatography type column apparatus to adsorb the iron on the apatite composition. One would be motivated to do so as it would not lead to any predictable results.

Regarding claims 14-16, Atsumi teaches the amount of iron to be adsorbed on the apatite composition. The weight percents of the metals are disclosed (Pg 41 table A). For instance, in example 1, 1 wt% and in example 11, 10 wt% of Fe was used per 135g of apatite (Pg 32 Para [0055]).

Atsumi does not teach the flow rate.

At the time of invention one having an ordinary level of skill in the art would envisage the use of an optimal or suitable volume or flow rate of the iron to be used in the process.

Claim 13 is rejected under 35 U.S.C. 103(a) as obvious over Ichitsuka et al. US5651884.

Ichitsuka teaches packing a column with an packing material of the formula $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_{2-2x}\text{F}_{2x}$ wherein, x is from 0.1 to 1. The use of this composition in a column for absorption separation by ion exchange and contacting with a liquid is taught.

At the time of invention it would have been obvious to use the adsorption composition of Ichitsuka to adsorb iron or any other material as it would not result in any unpredictable results.

Claims 13-17 are rejected under 35 U.S.C. 103(a) as obvious over Atsumi JP10118167, in view of Lennart et al. "Isolation of Phosphoproteins by Immobilizing metal..." Analytical Biochemistry 154, 250-254.

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Atsumi teaches an apatite composition on which an iron group is bonded onto. Atsumi also teaches the contacting the apatite and metal in an aqueous solution of a slurry. The weight percents of the metals are disclosed (Pg 41 table A). For instance, in example 1, 1 wt% and in example 11, 10 wt% of Fe was used per 135g of apatite (Pg 32 Para [0055]).

Atsumi does not teach the use of a column apparatus to support the iron on the apatite.

Lennart teaches the affinity of immobilized Fe^{3+} phase with phosphoproteins in Chromatography column (Abstract). Binding constants for other phosphor containing compounds with Fe^{3+} ions is also taught.

At the time of invention it would have been obvious to one having an ordinary level of skill in the art to use the Phosphorus compound of Atsumi as the stationary phase and the Fe^{3+} , with the prescribed loadings of Atsumi, as the mobile phase in the invention of Lennart. One would be motivated to do so because it would not lead to any unexpected results.

Response to Arguments

Applicant's arguments filed 05/06/2009 have been fully considered but they are not persuasive. Applicants argue that Atsumi teaches a change in the composition of the apatite when iron is supported. However, Atsumi only suggests that the ratio of calcium/phosphate "...sometimes fluctuates due to the type of metal element carried and the amount carried...". Atsumi does not expressly suggest that loading iron would result in an undesirable value of that ratio. Atsumi further teaches that the general

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formula for the apatite can be $\text{Ca}_{(10-z)}(\text{HPO}_4)_z(\text{PO}_4)_{6-z}\text{X}_{2-z} \cdot n\text{H}_2\text{O}$, where $z=0$ to 1 , $n=0$ to 1 . The applicants have not argued how Atsumi suggests that "z" will not be zero when iron is loaded or the loading of Iron would lead to an undesirable composition. Furthermore, the instant specification suggests that the composition of an apatite would not change as an iron ion is bonded to it.

Applicant's arguments filed 05/06/2009 have been fully considered but they are not persuasive. Applicants argue that in Atsumi Para. [0021] the ions in the variety of metal elements are carried by the interaction of the ion exchange with calcium ions. However, Atsumi teaches that an iron element and a variety of metals are carried on the apatite. In addition, Atsumi only teaches that the variety of metals are carried by the ion exchange interaction with the calcium ions. Atsumi does not suggest that the iron element was carried by the ion exchange interaction with calcium.

Applicant's arguments filed 05/06/2009 have been fully considered but they are not persuasive. Applicants argue that the adsorbent of the instant invention is used in a different field than the adsorbent of Atsumi. However, the composition of the instant invention is taught by the reference. One having an ordinary level of skill in the art would envisage that a composition which has the same chemical formula and bonding structure would possess the same physical properties. In any event, the composition is used as an adsorbent just like the instant composition. Even though Atsumi does not teach every possible use of the composition, the *use of* limitations would be inherent.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SYED IQBAL whose telephone number is (571)270-5857. The examiner can normally be reached on Monday to Thursday 7:30am EST to 6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman can be reached on 5712721358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wayne Langel/
Primary Examiner, Art Unit 1793

/S. I./
Examiner, Art Unit 1793